UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WASHINGTON

OSTERHAUS PHARMACY, INC., on behalf of itself and all others similarly situated, Plaintiff, v. UNITEDHEALTH GROUP INCORPORATED; OPTUM, INC.; OPTUMRX, INC.; OPTUMRX HOLDINGS, LLC, Defendants.	NO. **CLASS ACTION COMPLAINT** **JURY TRIAL DEMANDED**

Plaintiff Osterhaus Pharmacy, Inc. ("Osterhaus" or "Osterhaus Pharmacy" or "Plaintiff") brings this action on behalf of itself and all others similarly situated pursuant to Rule 23 of the Federal Rules of Civil Procedure against defendants UnitedHealth Group, Inc.; Optum, Inc.; OptumRx, Inc.; and OptumRx Holdings, LLC (collectively, "OptumRx"). Plaintiff seeks damages for violation of Sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1, 2, breach of contract, and breach of the covenant of good faith and fair dealing.

Plaintiff also seeks equitable and declaratory relief on the basis of claims for unjust enrichment, unconscionability, and quantum meruit.

I. NATURE OF THE ACTION

Plaintiff is a pharmacy that is bringing six claims on behalf of itself and a proposed class.

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The first is a tying claim under federal antitrust law. It is based on OptumRx denying pharmacy services providers access to its network of Medicare Part D beneficiaries to fill and dispense their prescriptions unless the pharmacy services providers also enter a second transaction, one involving a requirement that compels the pharmacy services providers to pay fees for the "opportunity" to provide other performance-related services. As explained below, those fees are called "DIR fees."

The second claim is for breach of contract. [redacted]

The third claim is for breach of the covenant of good faith and fair dealing. OptumRx forced pharmacy services providers—including Plaintiff and members of the proposed class—to agree to grant it discretion in setting metrics for and calculating the DIR fees pharmacy services providers must pay. OptumRx then exercised that discretion in bad faith and thereby breached the covenant.

The fourth claim is for a declaratory judgment that the DIR fees that OptumRx imposed are unconscionable.

The fifth claim is for unjust enrichment, requiring OptumRx to return to Plaintiff and members of the proposed class DIR fees that OptumRx's unconscionable contracts required them to pay.

A sixth claim is for quantum meruit, requiring OptumRx to pay Plaintiff and members of the proposed Class for the value of the DIR services they provided.

II. JURISDICTION, VENUE, AND INTERSTATE COMMERCE

1. Plaintiff brings this action pursuant to Section 4 of the Clayton Act, 15 U.S.C.§§ 15(a), to recover treble damages, cost of suit, and reasonable attorneys' fees for OptumRx's violation of Sections 1 and 2 of the Sherman Antitrust Act, 15 U.S.C. §§ 1, 2. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1337(a). The Court possesses supplemental jurisdiction over Plaintiff's claims for breach of covenant of good faith

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and fair dealing, unconscionability, unjust enrichment, and quantum meruit under 28 U.S.C. § 1367.

2. This Court has personal jurisdiction over the defendants pursuant to, among other statutes, Section 12 of the Clayton Act, 15 U.S.C. § 22.

3. Venue is proper in this Court pursuant to, among other statutes, Section 12 of the Clayton Act, 15 U.S.C. § 22, and 28 U.S.C. § 1391 because OptumRx regularly transacts business within this district, a substantial portion of the affected interstate trade and commerce discussed below has been carried out in this District, and OptumRx resides in this district.

4. The services at issue in this case are sold in interstate commerce. The unlawful activities alleged in this Complaint have occurred in, and have had substantial effect upon, interstate commerce in the United States.

III. PARTIES

5. Until January 1, 2022, Osterhaus operated as Osterhaus Pharmacy and M&M Care at 918 W Platt St #2, Maquoketa, IA. Osterhaus brings this action on behalf of itself individually and on behalf of a proposed class of pharmacy services providers, including but not limited to retail pharmacies, compounding pharmacies, and physician dispensaries but excluding mail order pharmacies, that:

1. are not part of the same corporate family as any of the three largest Pharmacy Benefits Managers ("PBMs"), as defined below, and so are independent of the three largest PBMs ("Independents");
2. are located in the United States; and
3. paid any DIR fees directly to OptumRx from December 18, 2019 until the time of trial.

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6. UnitedHealth Group Incorporated ("UnitedHealth Group") has been the fifth largest company in the United States for three consecutive years[1] and is one of the largest healthcare companies in the world. OptumRx is the name of UnitedHealth Group's PBM business, and it is one of the largest PBMs in the United States. While various legal entities within UnitedHealth Group perform PBM activities, they all do so under the OptumRx name. All are direct or indirect subsidiaries of UnitedHealth Group. UnitedHealth Group also owns one of the largest health insurance companies in the United States, UnitedHealthcare, and a mail order pharmacy that is the fourth largest pharmacy chain in the nation.[2] In 2022, the UnitedHealth Group corporate family generated over $324 billion in revenue.[3] OptumRx generated almost $100 million of this revenue.[4]

7. In 2022, UnitedHealth Group reported that OptumRx managed $124 billion in pharmaceutical spending.[5]

OptumRx Entities

8. OptumRx provides PBM services to Medicare Part D beneficiaries through numerous legal entities.

9. Defendant UnitedHealth Group Incorporated is a Delaware corporation with its principal place of business in Minnesota.

10. Defendant Optum, Inc. is a Delaware corporation.

11. Defendant OptumRx, Inc. is a California corporation.

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[1] *UnitedHealth Group*, Fortune 500 (2023), https://fortune.com/company/unitedhealth-group/fortune500/.

[2] Adam J. Fein, *The Top 15 U.S. Pharmacies of 2022: Market Shares and Revenues at the Biggest Companies*, Drug Channels (Mar. 8, 2023), https://www.drugchannels.net/2023/03/the-top-15-us-pharmacies-of-2022-market.html.

[3] Form 10-K, UnitedHealth Group Incorporated (2022), https://www.sec.gov/Archives/edgar/data/731766/000073176623000008/unh-20221231.htm.

[4] *Id.*

[5] *Id.*

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12. Defendant OptumRx Holdings, LLC is a limited liability company incorporated under the laws of Delaware.

13. UnitedHealth Group Incorporated directly or indirectly owns Optum, Inc., OptumRx, Inc., and OptumRx Holdings, LLC.

IV. FACTS

Independent Pharmacy Services Providers

14. In 1965, Bob and Ann Osterhaus purchased a family-owned pharmacy in Maquoketa, a town of a few thousand residents in Northeast Iowa. Their son, Matt Osterhaus, began working at the pharmacy in 1983, and eventually operated it with his wife Marilyn Osterhaus. In 2005, Bob Osterhaus was awarded the Remington Medal, the highest recognition given in the pharmacy profession, for his dedication. In 2005, Matt Osterhaus was awarded the Distinguished Achievement Award in Community Pharmacy Practice for his contributions to the conversion of the pharmacy into a pharmaceutical care model of practice. Not only has Osterhaus Pharmacy served the community, it also has trained the next generation of Iowa pharmacists. Since 1995, Osterhaus Pharmacy has served as a teaching site for Doctor of Pharmacy candidates including from the University of Iowa, located around 90 miles away. In 1997, Osterhaus Pharmacy, another pharmacy and the University of Iowa teamed up to offer a post graduate residency program—the first community-based residency in Iowa.

15. In January 2022, Matt Osterhaus sold Osterhaus Pharmacy because of PBMs' actions, including OptumRx's actions described in this complaint.

16. Bob, Ann, Matt, and Marilyn Osterhaus, like most Independent owners and pharmacists, are community leaders. They are actively involved in community- oriented public health, civic, and volunteer projects. They are committed to high-quality pharmacist care and to restoring, maintaining, and promoting the health and well-being of the public they serve.

17. Like Osterhaus Pharmacy, many Independents have a substantial impact on their communities. Independents meet the needs of their patient populations like no other institution. They provide wellness services, health screening, case management, medication

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synchronization, adherence packaging, personal delivery, long-term care support, immunizations, customized compounding services, and wound care products. Pharmacists and other providers at Independents routinely develop supportive relationships with their patients in ways that large corporate pharmacy services providers and mail-order pharmacists do not. Independents fully subscribe to their mantra: "We believe in doing what is right for the patient."

18. Independent pharmacy service providers work with patients to fill and dispense prescriptions, help manage medication, counsel patients on the use of both prescription and over-the-counter medications, and provide other health-related services, such as vaccine shots.

19. Independents are rooted in their communities. They are America's most accessible health care professional—and one of only a few in many parts of the country.[6] The independent pharmacy services provider plays an essential role in those areas, which frequently have shortages of healthcare workers.

20. Independents are closing in significant numbers in key locations across the nation. They face increasing financial pressure from PBMs, which keep reducing reimbursements to increase their own profits. The trend toward vertical consolidation in the pharmaceutical services industry has exacerbated matters, as PBMs now benefit by placing Independents at a disadvantage to their in-house pharmacies.

21. According to a University of Iowa study, 1,231 of the 7,624 independent rural pharmacies in the nation closed between 2003 to 2018.[7] That has left 630 rural communities that had at least one retail pharmacy in 2003 with none in 2018.[8] Since 2018, many more

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[6] *See* David M. Scott et al., *Assessment of Pharmacist's Delivery of Public Health Services in Rural and Urban Areas in Iowa and North Dakota*, Pharmacy Practice (2016); Megan Undeberg, et al., *A Case of Pharmacist-Led Care Team Interventions to Maximize Rural Patient Quality of Life*, Exploratory Research in Clinical and Social Pharmacy (Mar. 8, 2021).

[7] *Id*.

[8] Abiodun Salaki et al., *Update: Independently Owned Pharmacy Closures in Rural America 2003-2018*, University of Iowa Center for Rural Health Policy Analysis (July 2018),

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stores—often called "practices"—have closed. Those closures are forcing rural populations to travel greater distances to obtain needed medications, a particular hardship for low-income individuals and the elderly. [9]

22. Because of the loss of Independents, over 40% of counties in the United States are considered "pharmacy deserts," where most people must travel significant distances to reach the nearest pharmacy.[10] That can be insurmountable for people who lack transportation, time, or both, especially the poor and the elderly.

23. The loss of Independents has been particularly damaging in areas where they not only distributed prescription medications, but also delivered services such as immunizations, medication counseling and educational services, patient consultations, and treatment of mild illnesses amenable to over-the-counter medications.[11] During the Covid-19 pandemic, Independents were essential, dispensing vaccinations and testing for Covid-19. Closure of these pharmacy services providers can have a devastating impact on a community's access to healthcare services.

24. Even the Centers for Medicare and Medicaid Services ("CMS" or "Medicare"), which has a policy that it does not involve itself in contract negotiations, recently wrote: "Pharmacies serve a critical role in delivering health care and providing access to medications across the country. CMS is concerned about the sustainability of these businesses, especially small and independent pharmacies, and their potential closures that may leave pharmacy

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https://rupri.publichealth.uiowa.edu/publications/policybriefs/2018/2018%20Pharmacy%20Closures.pdf.

[9] *Id*.

[10] Kristine Pisikian, *How Pharmacy Deserts Impact Communities*, GoodRx Health (Mar. 30, 2022), https://www.goodrx.com/hcp/providers/pharmacy-deserts.

[11] Salaki, *supra* n. 8.

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services out of reach for many people, especially those in rural and underserved areas."[12] This letter is attached as Exhibit 1.

25. In contrast to the growth of national pharmacy chains, the market share of non-corporate-affiliated independent pharmacies has shrunk 50% over recent decades.[13]

Pharmacy Services

26. Pharmacy services providers vary in the services they provide. Typically, pharmacy services providers fill and dispense prescriptions and receive reimbursement for doing so—a service referred to as "Filling and Dispensing Services."

27. Some Independents also provide other services. They may support medication management, including with medication synchronization (synchronizing chronic medications to a single monthly pick-up date), medication therapy management, chronic disease monitoring, and multi-dose packaging that bundles medications. Those services can improve adherence to patients' medication regimen, benefiting the patients and reducing the costs of healthcare.

Medicare Prescription Drug Benefit (Part D)

28. Medicare is a federally funded health insurance program for persons aged 65 and older and persons with long-term disabilities. The Medicare prescription drug benefit, Medicare Part D ("Part D"), offers outpatient prescription drug coverage to Medicare beneficiaries across the country. Part D was enacted as part of the Medicare Modernization Act of 2003. Part D coverage is administered through private health plans ("Part D Sponsors" or "Plans") that contract with the federal government. Part D Sponsors are often run by large health insurance companies, including Aetna, Cigna, and UnitedHealthcare.

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[12] Letter from Office of the Administrator, Centers for Medicare & Medicaid Services, to Pharmacy Benefit Managers, Medicare Part D Plans, Medicaid Managed Care Plans, and Private Insurance Plans (Dec. 14, 2023).

[13] Alok Ladsariya, et al., *Meeting Changing Consumer Needs: The US Retail Pharmacy of the Future*, McKinsey & Company (Mar. 17, 2023), https://www.mckinsey.com/industries/healthcare/our-insights/meeting-changing-consumer-needs-the-us-retail-pharmacy-of-the-future.

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29. The Part D Sponsors, in turn, contract with corporate intermediaries—*i.e.*, PBMs—to administer their prescription drug benefits.

30. In 2023, approximately 52 million of the 66 million people covered by Medicare were enrolled in Part D.[14] Because Medicare recipients are prescribed more drugs on average than the population as a whole, Medicare beneficiaries constitute an outsized percentage of prescriptions filled in the United States.

PBMs: Powerful Middlemen
Standing Between Patients and their Medications

31. PBMs are powerful middlemen in the center of the pharmaceutical industry. They profit at nearly every stage of the drug distribution chain from manufacturing to filling and dispensing to patients.

32. PBMs act as intermediaries between Part D Plans, pharmacy services providers, and drug manufacturers. Part D Plans own or hire PBMs to negotiate drug pricing with manufacturers, and to determine the amount pharmacy services providers will be reimbursed for dispensing. PBMs use a series of rebates and fees along the supply chain to pocket the difference between what a PBM charges health plans for prescription drugs and what they pay the pharmacy — often called the "spread."

33. PBMs also offer administrative services to Part D Plans, including organizing networks of pharmacy services providers that contract with the Plans ("in-network pharmacy services providers") and determining the list of drugs ("formularies") covered by the Plans.

34. In sum, PBMs control every facet of the pharmaceutical filling and dispensing industry. They decide which pharmacy services providers can dispense drugs in Part D Plan networks, which drugs those pharmacy services providers will dispense, and the prices, discounts, and other terms of sale applicable to reimbursement of pharmacy services providers.

[14] *Medicare Enrollment Numbers*, Center for Medicare Advocacy (June 29, 2023), https://medicareadvocacy.org/medicare-enrollment-numbers/.

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35. Unfortunately, OptumRx, like other PBMs, abuses its control of the industry. In 2023, the Ohio Attorney General brought a lawsuit against PBM Express Scripts, describing the impact of PBMs as follows:

> PBMs are modern gangsters… . They were designed to protect and negotiate on behalf of employers and consumers after Big Pharma was criticized for overpricing medications, but instead they have absolutely destroyed transparency, scheming in the shadows to control drug prices on all sides of the market.[15]

36. Market consolidation and vertical integration have transformed PBMs and their corporate parents into sprawling entities with outsized market power and soaring profits.

37. CMS recently had to "urge plans and PBMs to engage in sustainable and fair practices with all pharmacies – not just pharmacies owned by PBMs" noting the "increasing level of vertical integration that is occurring among plans, PBMs, and their own pharmacies" can result in "anticompetitive behavior and place independent pharmacies at a disadvantage."[16]

38. Today, just six PBMs control 95% of the prescriptions filled in the United States. The "Big Three" PBMs—OptumRx, Express Scripts, and CVS Caremark—control more than 80% of the prescriptions filled in the United States ("PBM Market") and each generates tens of billions of dollars in annual revenue.

39. The market power of the Big Three PBMs has been magnified by a trend toward vertical integration. Each of the Big Three is now affiliated with a dominant health insurer: OptumRx (PBM) is affiliated with UnitedHealthcare (health insurer), Express Scripts (PBM) is affiliated with Cigna (health insurer), and CVS Caremark (PBM) is affiliated with Aetna (health insurer). Each of these affiliated health insurers—UnitedHealthcare, Aetna, and Cigna—

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[15] Complaint, State of Ohio, ex rel. Dave Yost v. Ascent Health Services LLC et al., No. 23-CV-H-03-00179 (Ohio Ct. Com. Pl. Mar. 27, 2023).

[16] Letter from Office of the Administrator, Centers for Medicare & Medicaid Services, to Pharmacy Benefit Managers, Medicare Part D Plans, Medicaid Managed Care Plans, and Private Insurance Plans (Dec. 14, 2023).

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administers Part D Plans for Medicare beneficiaries. These three health insurers cover almost half of Medicare Part D beneficiaries.

40. This vertical consolidation has served OptumRx well. It now controls not just the pricing of drugs, not just the selection of the drugs covered by Part D Plans, and not just the selection of pharmacy services providers in each Part D network; OptumRx also controls *access to almost a quarter of the Medicare beneficiaries enrolled in PBM-affiliated Plans.*[17] Independents must accept the increasingly anticompetitive pricing and contract terms set forth by OptumRx or face exclusion from its Part D network.

41. Not participating in OptumRx's network would severely limit a pharmacy services provider's access to a critical mass of patients. Participating in other networks is not a substitute—if an Independent does not accept the anticompetitive terms from OptumRx, it loses the patients in OptumRx's network. Those patients must take their prescriptions to a different pharmacy services provider to enjoy the benefits of their Medicare Part D Plans.

42. Further, beneficiaries do not choose Part D Plans based on DIR fees. The AARP, for example, offers a guide that recommends beneficiaries consider which pharmaceuticals a Plan covers, its cost, its customer services rating, and other factors.[18] Nowhere does it mention DIR fees.

43. To serve the millions of beneficiaries enrolled in OptumRx-affiliated Plans, Independents generally have no practical choice but to participate in the OptumRx network. Currently, over 67,000 pharmacies across the U.S. do so.[19]

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[17] Adam Fein, *The Top Pharmacy Benefit Managers of 2022: Market Share and Trends for the Biggest Companies*, Drug Channels (May 23, 2023), https://www.drugchannels.net/2023/05/the-top-pharmacy-benefit-managers-of.html.

[18] Kimberly Lankford, *How can I pick the best Medicare Part D prescription drug plan for my needs?* AARP (May 20, 2022), https://www.aarp.org/health/medicare-qa-tool/choosing-best-drug-plan-for-me.html.

[19] Form 10-K, UnitedHealth Group Incorporated (2022), https://www.sec.gov/Archives/edgar/data/731766/000073176623000008/unh-20221231.htm.

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44. OptumRx's vertical integration and the concentrated market create incentives for it to abuse its resulting market power. Its corporate family can and does benefit from imposing anticompetitive pricing on Independents and extracting services from them. If OptumRx goes too far, driving Independents out of business, UnitedHealth Group then benefits from eliminating rivals and steering its customers toward OptumRx's mail-order pharmacy. Either way, OptumRx wins and the Independents and patients lose.

Direct and Indirect Remuneration ("DIR") Fees: The Loophole

45. When a prescription drug is dispensed to a Medicare beneficiary (a patient), the beneficiary pays a co-payment to the pharmacy services provider at the point-of-sale. The pharmacy services provider then submits a claim for reimbursement to the PBM that acts on behalf of the beneficiary's Part D Plan. The PBM reimburses the pharmacy services provider based on a discounted average wholesale price of the drug, less fees and the amount of the patient's copayment.

46. The PBM is then reimbursed by the patient's Part D plan, which in turn submits a claim to CMS for reimbursement for the cost of the drug.

47. The Medicare statute provides that a sponsor or organization *shall* provide enrollees with access to negotiated prices used for payment for covered part D drugs, even if no benefits may be payable under the coverage with respect to such drugs. 42 U.S.C. § 1395w-102(d)(1)(A). The statute further states that *"*negotiated prices *shall* take into account negotiated price concessions, such as discounts or indirect subsidies, rebates, and direct or indirect remunerations, for covered part D drugs, and include any dispensing fees for such drugs.*"* 42 U.S.C. § 1395w-102(d)(1)(B) (emphasis added).

48. Congress was clear that it wanted all negotiated price concessions to be included in negotiated prices to beneficiaries at the point-of-sale. The Conference Report to the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 stated the following: "Qualified drug plans would be required to provide beneficiaries with access to negotiated prices (including all discounts, direct or indirect subsidies, rebates, other price concessions, or

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direct or indirect remunerations), regardless of the fact that no benefits may be payable." H.R. Rep. No. 108-391, at 438 (2003) (Conf. Rep.). The legislative history further added that "all PDP plans will be required to make available to their enrollees the benefit of *all* price discounts." H.R. Rep. No. 108-178, pt. 1, at 184 (2003) (emphasis added).

49. In 2014 rulemaking, CMS declared that "we believe that the best interpretation of statutory intent is that all pharmacy price concessions must be reflected in the negotiated price." 79 Fed. Reg. 1973.The concept of DIR was introduced by CMS, the federal agency that administers Medicare. CMS sought to increase transparency for the true price of prescription drugs and promulgated regulations to require Part D Sponsors and other entities to report to CMS all direct and indirect remuneration received for a drug—including all rebates or reimbursements received from drug manufacturers—so that CMS could base reimbursement rates to the Plans on the "true cost" of a prescription.

50. Before 2016, CMS required that the "negotiated price" for any drug—*i.e*., the price upon which patient cost-sharing is based at the point-of-sale—must be "reduced by those discounts, direct or indirect subsidies, rebates, other price concessions, and direct or indirect remuneration that the Part D sponsor has elected to pass through to Part D enrollees at the point- of-sale." 42 C.F.R. §423.100 (2014).

51. Effective January 1, 2016, CMS created what it intended to be a narrow exception to the rule. It excluded from the definition of negotiated price "those contingent price concessions that cannot reasonably be determined at the point-of-sale." 42 C.F.R. 423.100 (2016). CMS did not expect this change to have significant effects. But it did.

52. OptumRx exploited the new regulation to unlawfully extract huge sums of money from Independents.

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53. From 2010 to 2020, pharmacy DIR fees increased by more than 100,000%—that is, they grew more than 1,000 times larger. In 2021, DIR fees increased an additional 33% from 2020 levels to $12.6 billion.[20]

54. In 2018, CMS informed PBMs and Part D Sponsors that their manipulation of pharmacy price concessions after the point of sale is anti-competitive: "The one-sided nature of the pharmacy payment arrangements that currently exist also *creates competition concerns* by discouraging independent pharmacies from participating in a plan's network and thereby increasing market share for the sponsors' or PBMs' own pharmacies. Part D is a market based approach to delivery of prescription drug benefits, and relies on healthy market competition. Thus, adopting policies that promote competition is an important and relevant consideration in protecting Medicare beneficiaries and the Medicare trust fund from unwarranted costs. Market competition is best achieved when a wide variety of pharmacies are able to compete in the market for selective contracting with plan sponsors and PBMs." 83 Fed. Reg. 62,176 (emphasis added).

55. As the market power of the PBMs continues to grow, Independents continue to close in significant numbers amidst the stress from PBM-imposed DIR fees.[21]

56. OptumRx benefits whether Independents survive and continue to pay DIR fees or whether the fees drive Independents out of business. On one hand, OptumRx's corporate family profits from DIR fees in various ways, including by retaining them as a source of revenue. On the other hand, OptumRx's corporate family runs a large mail-order pharmacy. When other pharmacy services providers fail, OptumRx's corporate family faces less competition. Either way it benefits.

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[20] Medicare Payment Advisory Comm'n, *Medicare Payment Policy* (March 2023), https://www.medpac.gov/wp-content/uploads/2023/03/Mar23_MedPAC_Report_To_Congress_v2_SEC.pdf.

[21] Markian Hawryluk, *How Rural Communities are Losing Their Pharmacies*, KFF Health News (Nov. 15, 2021), https://kffhealthnews.org/news/article/last-drugstore-how-rural-communities-lose-independent-pharmacies/.

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A Square Peg in a Round Loophole

57. For over half a decade, OptumRx has imposed increasing DIR fees on Independents based on "performance criteria" metrics, many of which make no sense for pharmacy services providers.

58. Realizing an opportunity to pilfer money from Independents purportedly under the 2016 CMS changes, OptumRx fabricated fees that "could not be calculated at the point of sale."

59. OptumRx imposed contracts on Independents in which they are assessed DIR fees, supposedly based on their performance and purportedly to encourage better performance by pharmacy services providers. OptumRx's system for assessing fees means that DIR fees are not known until some time after pharmacy services providers fill and dispense medications because the fees supposedly rely on patient data and outcomes. Therefore, according to OptumRx, DIR fees cannot "reasonably be determined at the point-of-sale."

60. Various attributes of OptumRx's DIR fees are striking. First, they force pharmacy services providers to *pay* for the opportunity to provide services ("DIR Services"). OptumRx charges Independents DIR fees in amounts that depend on how it assesses their performance.

[redacted]

61. A second striking attribute of DIR fees is that they coerce pharmacies to produce outcomes over which they have little or no control. Although OptumRx claims that its "performance criteria" are designed to measure pharmacy performance, many of them either do not do so or they do so poorly. OptumRx's metrics for measuring pharmacy performance are loosely based on Medicare's Star Rating system, Medicare's system for rating the performance of *Part D Plans*. The "performance criteria" monitor things such as adherence to certain prescription drugs, including for hypertension, cholesterol, diabetes. OptumRx will also monitor generic compliance rates.

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62. But the Star Ratings were developed to rate health plans, not pharmacies. As a result, many of the performance criteria established by OptumRx make little or no sense for pharmacies. A large number are outside pharmacy control—including because it is dependent upon physician prescriptions—or are most heavily influenced by patient characteristics—such as poverty or access to information.

63. For example, for a pharmacy to achieve a high score on statin adherence (which lowers cholesterol), *a physician or other provider with prescriptive authority* (hereinafter a physician) must prescribe a statin as part of a cholesterol program. But physicians may have good reasons not to do this, including if a statin is contraindicated due to drug interactions for a particular condition (such as prescription drugs treating HIV). In any event, the pharmacy whose performance is purportedly being measured has little or no control over whether a physician prescribes a particular medication. Pharmacists do not have prescriptive authority and thus cannot prescribe medications and cannot control their "performance" under OptumRx's standards.

64. Other factors OptumRx uses, such as generic dispense rates, are not within the sole control of the pharmacy and are poorly designed to encourage better performance. Yet pharmacies are forced to pay to provide those services to be part of the network. For example, physicians may prescribe branded medications and instruct a pharmacist to "dispense as written." Under those circumstances, a pharmacist must dispense the branded drug, but they will be punished and forced to pay higher DIR fees even though they have no influence over the decision to prescribe branded drugs.

65. The purported performance standards particularly harm specialty pharmacies, such as those treating patients with the most severe diseases, including cancer and HIV. Specialty pharmacies often do not dispense generic drugs or common "maintenance medications," like statins. Yet OptumRx still penalizes them for failing to do so.

66. Not only are many of the metrics nonsensical, but so are the ways in which OptumRx applies them. Application of performance metrics is at OptumRx's complete

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discretion—a discretion OptumRx exercises in bad faith. For example, OptumRx penalizes an Independent on adherence if a patient stays at a facility covered by Medicare Part A and fills prescriptions at that facility.

67. In sum, the practical effect of the DIR fees is that Independents are forced to pay to provide DIR Services, and the amount they pay is in large part arbitrary, unexplained, unfairly calculated, and untimely.

68. The upshot of OptumRx's unsound methodology is that pharmacy services providers are unfairly treated to their financial disadvantage. OptumRx gains an unfair economic advantage both in revenue to OptumRx and in passthrough payments to Plans, enhancing OptumRx's competitive posture. OptumRx also increases its profits at the expense of the government and Medicare Part D patients—the elderly and the infirm. In fact, CMS, despite its policy of not interfering in contract negotiations, recently noted that there have been "an increasing number of concerns about certain practices by some plans and pharmacy benefit managers (PBMs) that threaten the sustainability of many pharmacies, impede access to care, and put increased burden on health care providers."[22]

The Tie

69. Given the option, Independents would choose to provide Filling and Dispensing Services without also having to pay to provide DIR Services. But OptumRx uses its market power to deprive Independents of that option. OptumRx affirmatively withholds the maximum amount it can assess in DIR fees and the only choice Independents have to not pay DIR fees is to decline to participate in OptumRx's network.

70. *Separate Markets*. Separate markets exist for Independents (1) to acquire access to PBMs' networks of beneficiaries to provide Filling and Dispensing Services and (2) to acquire the opportunity to provide DIR Services to the Plans that PBMs serve. Neither one is reasonably

[22] Letter from Office of the Administrator, Centers for Medicare & Medicaid Services, to Pharmacy Benefit Managers, Medicare Part D Plans, Medicaid Managed Care Plans, and Private Insurance Plans (Dec. 14, 2023).

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interchangeable with the other. A PBM can increase its prices to Independents for access to provide Filling and Dispensing Services to its network of beneficiaries without those Independents choosing instead to acquire the opportunity to provide DIR Services to the Plans that the PBM serves and *vice-versa*. A PBM with substantial power in only one of the two markets could thus impose a small but significant non-transitory increase in prices without having substantial power in the other market.

71. Similarly, separate markets exist for Independents (1) to acquire access to the OptumRx PBM network of beneficiaries to provide Filling and Dispensing Services and (2) to acquire the opportunity to provide DIR Services to the Plans that the OptumRx PBM serves. Neither one is reasonably interchangeable with the other. OptumRx as a PBM can increase its prices to Independents for access to provide Filling and Dispensing Services to its network of beneficiaries without those Independents choosing instead to acquire the opportunity to provide DIR Services to the Plans that OptumRx as a PBM serves and *vice-versa*. The OptumRx PBM can thus use substantial power in only one of the two markets to impose a small but significant non-transitory increase in prices without having substantial power in the other market.

72. *Power in the Tying Market*. OptumRx has substantial power in the market for access to beneficiaries for filling and dispensing Medicare Part D prescriptions (the "Tying Market").

73. Market circumstances establish OptumRx's substantial market power. It is one of the largest PBMs in the United States. The market is concentrated with the collective market share of the top three PBMs at 80% or more. All three of the dominant PBMs impose DIR fees on Independents as a condition of obtaining reimbursement from Plans for filling and dispensing Medicare Part D prescriptions.

74. Independents generally cannot afford to reject the terms OptumRx imposes for participating in its Medicare Part D network to provide Filing and Dispensing Services. They would lose too many sales to potential patients.

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75. OptumRx has even more market power than its market share would ordinarily confer. There are multiple reasons. One of them is that the other dominant PBMs also impose DIR fees. Such parallel anticompetitive behavior is common in markets with a small number of dominant players.

76. A second reason is that Independents generally cannot complete transactions with beneficiaries in OptumRx's Medicare Part D by using a different network. They must be part of OptumRx's network or forego reimbursement from the relevant Plan. As a result, this market is different from many others. An automotive repair shop, for example, can avoid a car part manufacturer's tie by purchasing parts from a rival manufacturer. It will lose few, if any, customers or sales by doing so. Independents cannot do the same to avoid losing Medicare Part D customers in OptumRx's network.

77. Independents are purchasers in the Tying Market. They pay OptumRx to obtain the opportunity to provide Filling and Dispensing Services to its network of beneficiaries. Those payments involve "spread pricing." OptumRx retains a portion of the payments it receives to reimburse Independents. The difference—between the amount OptumRx obtains and the amount it passes on to an Independent—is called the "spread." Independents pay the "spread" to OptumRx. The "spread" is separate from and in a different market than DIR fees.

78. *Coercion in the Tied Market*. OptumRx used its substantial power in the market for filling and dispensing Medicare Part D prescriptions to coerce Independents to agree to pay to provide DIR Services. The market for DIR Services is the "Tied Market."

79. OptumRx's tie (the "Tie") conditions transactions in the Tying Market on transactions in the Tied Market. OptumRx will not let Independents obtain access to beneficiaries in its Medicare Part D network—transactions in the Tying Market—unless the Independents also agree to pay to provide DIR Services—transactions in the Tied Market.

80. In the absence of the Tie—and OptumRx's power in the Tying Market— no Independent would agree to *pay* for the opportunity to provide DIR Services. Some would choose not to provide DIR Services even if they would be paid to do so. The rest would charge

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to provide DIR Services, and they would demand enough compensation to cover their costs (plus some profit). Independents provide, and in the absence of the Tie they would provide, different kinds and degrees of DIR Services.

81. OptumRx's successful coercion directly establishes OptumRx's substantial power in the Tying Market and its extension of that substantial power into the Tied Market. OptumRx's ability to use its substantial power in the Tying Market to coerce Independents to agree to pay DIR fees on terms they would otherwise reject is by definition market power.

82. *Distinct Markets*. The Tying Market and Tied Market are distinct. As noted above, in the absence of the Tie, many Independents would acquire access to OptumRx's network of Medicare Part D beneficiaries to provide Filling and Dispensing Services without also paying to provide DIR Services. That is what many Independents did before OptumRx imposed its Tie. It is what they still do outside of the Medicare Part D context. The pervasive imposition of DIR fees by PBMs is a distinctive feature of Medicare Part D Plans over the last seven years.

83. *Economic Benefit*. The DIR fees benefit OptumRx in many ways. The OptumRx corporate family, including UnitedHealth Group, receives and retains DIR fees. Further, those fees can to some extent improve management of the health of Part D beneficiaries, decreasing the costs to OptumRx's Plans, including those managed by UnitedHealth Group. DIR Services can improve adherence, increase the filling and dispensing of prescriptions, and thereby generate revenue for OptumRx's corporate family. And the DIR fees give OptumRx's pharmacies a competitive advantage over Independents on costs, increasing its pharmacies' sales volumes.

OptumRx's Unconscionable Contracts

84. OptumRx imposes DIR fees and forces pharmacy services providers to provide DIR Services at a loss through contracts that are not the subject of arms-length negotiation. OptumRx leverages its market power, vertical integration with the Part D Plans, and access to networks of Medicare beneficiaries to impose numerous, lengthy, one-sided contracts to the Independents as part of a "take it or leave it" package. Independents cannot afford to push

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back against OptumRx because they risk losing access to beneficiaries. The opposite is not true—OptumRx can steer and prefers to steer patients to its own mail-order pharmacy. To be sure, community members suffer as a result—from losing pharmacy services or receiving inadequate services. Such decreases in output and quality are standard consequences when businesses with market power exclude competition and artificially inflate prices.

85. The OptumRx "contracts" consist of numerous documents, which [redacted]

86. These contracts are one-sided, creating an extraordinary imbalance in obligations. For example, under the contracts OptumRx at times reimburses the pharmacy services providers *for less than their cost of acquiring drugs.* In other words, OptumRx forces pharmacy services providers to fill prescriptions at a loss. When accounting for administrative costs and DIR fees, it can become financially crippling to fill prescriptions at below acquisition cost under the terms of the OptumRx contracts.

87. OptumRx sets the terms of its contracts with Independents. There is no meaningful opportunity to negotiate, as Independents are forced to accept inequitable terms or to lose access to millions of beneficiaries serviced by OptumRx and the Plans with which it works. OptumRx leverages its market power and unique position as a corporate affiliate of UnitedHealth Group to coerce the Independents to accept the imposition of DIR fees.

88. The OptumRx contract terms are not merely one-sided and oppressive. OptumRx has also breached its contracts with Independents [redacted]

89. Medicare Part D requires Part D Plans—and their PBM representatives— to contract with any willing pharmacy that meets the Plan's standard terms and conditions. 42 CFR § 423.120(a)(8)(i). Moreover, the terms must be "reasonable and relevant." 42 CFR § 423.505. Numerous states have passed their own "any willing provider" statutes, and OptumRx's contracts set forth those laws. Yet pursuant to the terms of the contract, OptumRx has

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arbitrary, retroactive DIR fees that are by no means "reasonable." Likewise, OptumRx's reimbursement rates for the two tied products are often below the acquisition cost of the drug: terms that reimbursement below cost are clearly unreasonable. Moreover, many Independents are willing and ready to provide Filling and Dispensing Services, but not DIR Services. OptumRx requires Independents to do both.

90. Likewise, federal law requires prompt payment of "clean claims" (claims for reimbursement with no defect or impropriety) that are submitted electronically by an Independent within 14 days after the claim has been received, or within 30 days of receiving any other claim. 42 U.S.C. §1395w-112. Yet Independents must wait for their reimbursements.

91. OptumRx seeks to shield its unlawful conduct from being challenged by including in its contracts with Independents a forced arbitration clause with several unconscionable terms. They include giving OptumRx the power to change the terms of the clause unilaterally, to force Independents to submit to expensive arbitration, even to determine the unconscionability of the arbitration provisions, and to impose prohibitive costs on Independents that initiate arbitration. A court[23] has recently describe OptumRx's arbitration scheme as follows:

> [I]n all but the most substantial disputes the cost of proceeding to arbitration will substantially outweigh any benefit that could be achieved in arbitration and that this will undoubtedly have a substantial chilling effect upon pharmacies presenting objectively meritorious positions. "You can't fight City Hall so why try" appears to be the result that this scheme creates. This is the product of a one sided agreement foisted upon pharmacies who need to make a deal with Optum or have a substantial part of a market closed to them and this is fundamentally unfair.

[23] Optum, RX, Inc. v. Marinette-Menominee Prescription Center, Ltd., 2023 WL 4485615, at *1 (Wis. Cir. June 30, 2023).

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V. CLASS ALLEGATIONS

92. Plaintiff brings this action on behalf of itself and all other similarly situated Independents pursuant to Rule 23 of the Federal Rules of Civil Procedure as a representative of a class (the "Class") defined as follows:

> All pharmacy services providers in the United States that are not members of the same corporate family as a Big Three PBM and that have paid DIR fees directly to OptumRx from September 26, 2019 until the time of trial (the "Class Period").

93. Thousands of Independents have entered contracts with OptumRx that impose unlawful DIR fees during the Class Period. The Class is so numerous that joinder is impracticable.

94. Plaintiff's claims are typical of claims of the Class.

95. Plaintiff and all members of the Class were injured by the unlawful DIR fees imposed by OptumRx.

96. Plaintiff will fairly and adequately protect and represent the interests of the Class. The Plaintiff's interests are not antagonistic to those of the Class.

97. Plaintiff is represented by counsel who are experienced and competent in the prosecution of antitrust and other class actions.

98. Questions of law and fact are common to members of the proposed Class and predominate over questions, if any, that may affect only individual members. OptumRx has acted on grounds generally applicable to the entire Class. Such generally applicable conduct is inherent in OptumRx's unlawful contracts and anticompetitive conduct more fully alleged herein.

99. Questions of law and fact common to the class include:

a) Whether OptumRx has market power;

b) Whether OptumRx imposed an unlawful tie;

c) Whether OptumRx violated its contracts;

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d) Whether OptumRx's actions breached the covenant of good faith and fair dealing inherent in its contracts;

e) Whether OptumRx's imposition of DIR fees was unconscionable;

f) Whether Plaintiff and members of the proposed class have been injured by paying unlawful DIR fees; and

g) The proper measure of damages.

100. The Class is readily identifiable from information and records in the possession of OptumRx.

101. Class treatment is a superior method for the fair and efficient adjudication of the controversy than individual treatment in that, among other things, class treatment will permit a large number of similarly situated Independents to prosecute their common claims in a single forum simultaneously, efficiently, and without the unnecessary duplication of effort and expense that numerous individual actions would engender. The benefits of proceeding through the class mechanism, including providing entities with a method for obtaining redress for claims that might not be practicable for them to pursue individually, substantially outweigh any difficulties that might arise in management of this class action.

102. Plaintiff knows of no difficulties in maintenance of this action on a class basis.

VI. CAUSES OF ACTION

First Claim for Relief
Tying, Sherman Act, 15 U.S.C. § 1, § 2

103. Plaintiff incorporates by reference the allegations contained in the preceding paragraphs as if fully set forth herein.

104. OptumRx has tied access to its network of beneficiaries for Filling and Dispensing Services to purchase of the opportunity to provide DIR Services.

105. Filling and Dispensing Services and DIR Services are distinct.

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106. As a direct and proximate result of the foregoing conduct, Plaintiff and members of the proposed Class have been injured by paying artificially inflated prices for the opportunity to provide DIR Services rather than receiving compensation for providing DIR Services.

Second Claim for Relief
Breach Of Contract

107. Plaintiff incorporates by reference the allegations contained in the preceding paragraphs as if fully set forth herein.

108. OptumRx entered contractual relationships with Plaintiff and members of the proposed Class [redacted]

109. OptumRx regularly violates Any Willing Provider regulations in Medicare, including 42 U.S.C. § 1395w-104(b)(1)(A) and 42 C.F.R. 423.120(a)(8)(i).

110. OptumRx also violates Medicare regulations requiring prompt payment of claims. 42 C.F.R. 423.520.

111. OptumRx also regularly violates state laws regulating pharmacy benefit managers, including any willing provider laws and prompt payment laws.

Third Claim for Relief
Breach of Implied Covenant of Good Faith and Fair Dealing

112. Plaintiff incorporates by reference the allegations contained in the preceding paragraphs as if fully set forth herein.

113. OptumRx entered contractual relationships with Plaintiff and members of the proposed Class and owed them a duty to act in good faith and deal fairly.

114. The conduct of OptumRx described in this complaint violated the implied covenant of good faith and fair dealing, including because OptumRx exercised discretion and performed its contractual obligations in bad faith and in a manner that denied Plaintiff and members of the proposed Class the benefit of their bargains.

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115. Such acts and omissions leading to OptumRx's breach of duty to deal in good faith and fairly with Plaintiff and members of the proposed Class were the actual and proximate cause of harm to them.

Fourth Claim for Relief
Unconscionability

116. Plaintiff incorporates by reference the allegations contained in the preceding paragraphs as if fully set forth herein.

117. Plaintiff seeks a declaratory judgment from this Court stating that the imposition of DIR fees was unconscionable.

Fifth Claim for Relief
Unjust Enrichment

118. Plaintiff incorporates by reference the allegations contained in the preceding paragraphs as if fully set forth herein.

119. Plaintiff and members of the proposed Class conferred benefits on OptumRx by providing Filling and Dispensing Services and DIR Services to beneficiaries covered by Plans it administered.

120. OptumRx benefited from those services at the expense of Plaintiff and members of the proposed Class by receiving compensation under its contracts with its Plans and otherwise.

121. It would be unjust to allow OptumRx to keep the benefits of the services of Plaintiff and members of the proposed Class.

Sixth Claim for Relief
Quantum Meruit

122. Plaintiff incorporates by reference the allegations contained in the preceding paragraphs as if fully set forth herein.

123. Plaintiff and members of the proposed Class conferred benefits on OptumRx by providing Filling and Dispensing Services and DIR Services to beneficiaries covered by Plans it administered.

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124. OptumRx accepted the services or materials.

125. The unconscionability of OptumRx's actions renders the contracts between Plaintiff and members of the proposed Class and OptumRx unenforceable as they relate to DIR fees.

126. OptumRx should be required to pay Plaintiff and members of the proposed Class for the value of the DIR Services they provided.

VII. DEMAND FOR RELIEF

Plaintiff respectfully asks this Court:

A. to enter judgment awarding damages to Plaintiff and members of the proposed Class in an amount to be determined, and trebled as provided in Section 4 of the Clayton Act, 15 U.S.C. § 15(a), on their federal antitrust claims;

B. to award Plaintiff and members of the proposed Class restitution;

C. to award Plaintiff and members of the proposed Class the cost of this suit, including reasonable attorney's fees, as provided in Section 4 of the Clayton Act, 15 U.S.C. § 15, on their federal antitrust claims; and

D. to order such other and further relief as this Court deems proper and just.

VIII. DEMAND FOR JURY TRIAL

Pursuant to Fed. R. Civ. P. 38(b), Plaintiff demands a trial by jury on all issues so triable.

RESPECTFULLY SUBMITTED AND DATED this 18th day of December, 2023.

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- Exhibit 1 -

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
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OFFICE OF THE ADMINISTRATOR

December 14, 2023

Dear Pharmacy Benefit Managers, Medicare Part D Plans, Medicaid Managed Care Plans, and Private Insurance Plans:

The Centers for Medicare & Medicaid Services (CMS) values your partnership in providing health care coverage and access to essential treatments, including prescription medications, to millions of people. However, we are hearing an increasing number of concerns about certain practices by some plans and pharmacy benefit managers (PBMs) that threaten the sustainability of many pharmacies, impede access to care, and put increased burden on health care providers. We are writing to share these concerns and to encourage you to work with providers and pharmacies to alleviate these issues and safeguard access to care. This is especially important for vaccines and treatments that can prevent and treat influenza, COVID-19, and RSV as we enter the winter respiratory virus season.

Pharmacies serve a critical role in delivering health care and providing access to medications across the country. CMS is concerned about the sustainability of these businesses, especially small and independent pharmacies, and their potential closures that may leave pharmacy services out of reach for many people, especially those in rural and underserved areas. With respect to the Medicare Part D program, CMS finalized a pharmacy price concessions provision in the Contract Year 2023 Medicare Advantage and Part D final rule that is expected to lower total beneficiary out-of-pocket costs, provide meaningful price transparency, better reflect pharmacy payment arrangements, and enable CMS to assess the payment practices of Part D plan sponsors and PBMs with respect to pharmacies under the Medicare Part D program.[1] This provision takes effect January 1, 2024, and requires the application of all pharmacy price concessions to the negotiated price at the point of sale. CMS has heard many concerns regarding the potential impact on pharmacy cash flow upon implementation of this provision, and we finalized a one-year delay in the effective date of the policy to provide sufficient time for implementation. **We continue to hear urgent concerns from pharmacies, and we strongly encourage Part D plan sponsors and their PBMs to make necessary cash flow arrangements with network pharmacies in preparation for these upcoming changes. In addition, we will closely monitor**

[1] See final rule titled, "Medicare Program; Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs" (CMS-4192-F) (87 FR 27704) at: https://www.govinfo.gov/content/pkg/FR-2022-05-09/pdf/2022-09375.pdf.

plan compliance with pharmacy access and prompt payment standards to ensure that all people with Medicare Part D continue to have access to pharmacies and medications.[2]

We have also heard from pharmacies that the amount plan sponsors and PBMs that serve plans in Medicare, Medicaid, and the Children's Health Insurance Program (CHIP), and plans offered through the Marketplaces pay pharmacies for some vaccine administrations is causing many pharmacies and other providers of vaccines to lose money administering vaccines, discouraging them from providing these vaccines. **Particularly as we encourage people to get vaccinated against influenza, COVID-19, and RSV this year, CMS is very concerned about payment practices that may impede access to recommended vaccinations, and it is imperative that plans and PBMs take immediate steps to ensure adequate payment for and access to vaccines.**

In addition, we know that the increasing level of vertical integration that is occurring among plans, PBMs, and their own pharmacies has the potential to result in anticompetitive behavior and place independent pharmacies at a disadvantage. **We urge plans and PBMs to engage in sustainable and fair practices with all pharmacies – not just pharmacies owned by PBMs – and we are closely monitoring plan compliance with CMS network adequacy standards and other requirements.**

We have also heard of concerns from stakeholders and consumers that privately insured patients and providers continue to experience a difficult time navigating plan and issuer exceptions processes for medically necessary contraceptive drugs, items, and services required to be covered under the Affordable Care Act. In addition, we have seen plans and issuers impose cost sharing on coverage of preventive services due to claims being submitted with unrelated diagnostic codes or because the provider did not use a specific preventive care procedure code required by the plan or issuer. We are investigating these concerns within our jurisdiction. **We urge plans, issuers, and PBMs to check their processes and systems to ensure they are providing full coverage, without cost sharing, of preventive services, as required by federal law.**

We also want to highlight that most children enrolled in Medicaid and CHIP have coverage of all routine Advisory Committee on Immunization Practices (ACIP)-recommended vaccines and vaccinations determined to be medically necessary for beneficiaries eligible for the Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) benefit without cost sharing. Most adults enrolled in Medicaid and CHIP have coverage of FDA-approved and ACIP-recommended vaccinations without cost sharing because requirements established in the Inflation Reduction Act (IRA) became effective on October 1, 2023. This new IRA adult vaccine coverage applies to all types of ACIP recommendations. Additional information can be found in our recent guidance and fact sheet on the new IRA vaccine coverage for adults. Additionally, COVID-19 vaccinations are mandatorily covered for nearly all Medicaid and CHIP beneficiaries through September 30, 2024, in accordance with the American Rescue Plan Act of 2021. **We urge plans, as well as states, to ensure that their guidance and systems reflect this coverage.**

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[2] See Health Plan Management System (HPMS) memo titled, "Application of Pharmacy Price Concessions to the Negotiated Price at the Point of Sale Beginning January 1, 2024" at: https://www.cms.gov/about-cms/information-systems/hpms/hpms-memos-archive-weekly/hpms-memos-wk-2-november-6-10.

Finally, we often hear concerns about the impact of plans' utilization management tools, including prior authorization. The inappropriate use of these tools can impede access to needed care for people and delay essential treatments, as well a take clinician time away from direct care. Providers, especially those in rural areas, report that these plan practices have become increasingly unsustainable and burdensome. Earlier this year, CMS finalized vital protections that will be effective on January 1, 2024, to ensure Medicare Advantage enrollees have timely access to needed care and to crack down on harmful disruptions to care. We have also proposed new requirements to improve access to patient health information and to address avoidable delays in patient care by streamlining the electronic exchange of health care data and processes related to prior authorization for Medicare Advantage organizations, state Medicaid and CHIP Fee-for-Service programs, Medicaid managed care plans and CHIP managed care entities, and Qualified Health Plan issuers on the Federally Facilitated Marketplaces. **We remind plans that CMS will be conducting robust oversight to ensure Medicare Advantage organizations are complying with these new requirements, and we continue to review comments received on the additional proposals from the second rulemaking.**

Thank you for your attention to these issues.

Sincerely,

Chiquita Brooks-LaSure
Administrator

Jonathan Blum
Principal Deputy Administrator and
Chief Operating Officer

Meena Seshamani, M.D., Ph.D.
Deputy Administrator and Director
Center for Medicare

Daniel Tsai
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